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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,547	08/25/2003	Abraham Mittelman	12354/9	5161

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EXAMINER	
DIBRINO, MARIANNE NMN	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 01/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/648,547	MITTELMAN ET AL.	
	Examiner	Art Unit	
	DiBrino Marianne	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-19 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-19 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 2, drawn to a method of identifying an immunodominant epitope of an MHC class I molecule or a method of producing a poplypeptide useful for eliciting an immune response against an antigen in a host, said immune response restricted by MHC class I, classified in Class 435, subclass 7.1.

II. Claim 3, drawn to a method of identifying an immunodominant epitope of an MHC class II molecule or a method of producing a polypeptide useful for eliciting an immune response against an antigen in a host, said immune response restricted by MHC class II, classified in Class 435, subclass 7.2.

III. Claims 14-16, drawn to a method of eliciting a therapeutic immune response to an antigen comprising administering a polypeptide that binds to an MHC class II molecule, classified in Class 424, subclass 185.1 and Class 514, subclass 14.

IV. Claims 17-19, drawn to a method of eliciting a therapeutic immune response to an antigen comprising administering a polypeptide that binds to an MHC class I molecule, classified in Class 424, subclass 185.1 and Class 514, subclass 15.

Claims 1 and 4-12 link inventions I and II. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims, claims 1 and 4-12.

Claim 13 links inventions III and IV. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims, claim 13.

Upon the allowance of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claim will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim depending from or including all the limitations of the allowable linking claim is presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211,1215,170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

2. The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the Examiner before the patent issues. See MPEP § 804.01.

3. Inventions I, II, III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case these methods are different methods with different method steps, ingredients and endpoints. The methods of Inventions I and II are *in vitro* methods of epitope identification and production, whereas the methods of Inventions III and IV are *in vivo* peptide administration methods. The different inventions are methods of identifying an immunodominant epitope/useful immunogenic peptide (Groups I and II) that binds to class I MHC (Group I) or class II MHC (Group II) and elicits a response in context of the said MHC molecule, or methods for eliciting a therapeutic immune response to an antigen comprising administering a polypeptide (Groups III and IV) that binds to class I MHC (Group III) or class II MHC (Group IV) and elicits a response in the context of the said MHC molecule. For example, the method of Invention I comprises a step of examining amino acid sequences within the antigen for binding affinity to an MHC class I molecule and selecting one that binds with high affinity, whereas the method of Invention II comprises a step of examining amino acid sequences within the antigen for binding affinity to an MHC class II molecule and selecting one that binds with high affinity. The peptides that bind to MHC class I are of a different length than those

that bind to MHC class II, and an amino acid sequence that binds to MHC class I with high affinity would not bind to MHC class II with high affinity or at all. For example, although the Inventions of Groups III and IV are not disclosed in the instant specification as being capable of use together, in some instances, it may be desirable to generate both class I MHC and class II MHC restricted responses to an antigenic protein. However, the Inventions of Groups III and IV have different modes of operation, different functions and different effects, *i.e.,* the peptides of different length and composition are bound to different MHC class molecules and elicit immune responses that are class I MHC restricted such as CTL activation, proliferation and (CTLp) differentiation, or MHC class II restricted such as activation of Th cells for antibody production. CTL are capable of lysing target cells directly and in context of MHC class I, whereas Th cells provide help in an MHC class II restricted fashion for the humoral response which produces antibodies capable of recognizing nominal antigen (antigen by itself not in the context of MHC).

4. Because these inventions are distinct for the reasons given above and the search required for any group from Groups I-IV is not required for any other group from Groups I-IV and Groups I-IV have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

5. **If Applicant elects the Invention of Group I or of Group II**, Applicant is further required to (1) elect a single disclosed species of method steps for: examining amino acid sequences within an antigen for binding affinity to an MHC molecule *and* examining amino acid sequences within the antigen to determine sequence similarity to the host proteome (for example, examining amino acid sequences within the antigen for binding affinity to an MHC class I molecule by predictive method of comparing amino acid sequences within the antigen to a consensus MHC binding sequence, examining sequence similarity by comparing overlapping amino acid sequences 4-10 amino acid residues in length wherein the short overlapping amino acid sequences are offset by 1 or 2 amino acid residues) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because they are different method steps.

6. **If Applicant elects the Invention of Groups III or IV**, Applicant is further required to (1) elect a single disclosed species of method steps for: examining amino acid sequences within an antigen for binding affinity to an MHC molecule, *and* examining amino acid sequences within the antigen to determine sequence similarity to the host proteome (for example, examining amino acid sequences within the antigen for binding affinity to an MHC class I molecule by predictive method of comparing amino acid sequences within the antigen to a consensus MHC binding sequence, examining sequence similarity by comparing overlapping amino acid sequences 4-10 amino acid

residues in length wherein the short overlapping amino acid sequences are offset by 1 or 2 amino acid residues) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because they are different method steps.

7. **In addition, if Applicant elects the Invention of Groups III or IV**, Applicant is further required to (1) elect a single disclosed species of antigen (a specific antigen, for example a viral antigen such as E7 from HPV) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because they have different structures and elicit immune responses against different agents.

8. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

9. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

10. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. 809.02(a).

11. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

12. Applicant is reminded that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

14. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 571-272-0842. The Examiner can normally be reached on Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Y. Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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